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| **ONR GUIDE** | | | |
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1. INTRODUCTION­
   1. ONR has established its Safety Assessment Principles (SAPs) which apply to the assessment by ONR specialist inspectors of safety cases for nuclear facilities that may be operated by potential licensees, existing licensees, or other duty-holders. The principles presented in the SAPs are supported by a suite of guides to further assist ONR’s inspectors in their technical assessment work in support of making regulatory judgements and decisions. This technical assessment guide is one of these guides.
2. Purpose and scope
   1. The purpose of this Technical Assessment Guide (TAG) is:

* To provide good practice expectations to assist the Office for Nuclear Regulation’s (ONR) Inspectors in judging the adequacy of a licensee's arrangements and outputs under Licence Condition (LC) 15, which requires the licensee to periodically review safety cases (see the *Licence Condition Handbook* [1]).
* To add more detailed guidance to the How2 Business Management System Guide Guidance: LC15 Periodic review [2].
  1. The guidance does not address the following:
* Requirements for periodic reviews arising from legislation other than the Nuclear Installations Act 1965 (as amended) (NIA) / LC15, e.g.
* Control of Major Accident Hazards Regulations 1999 and the Control of Major Accident Hazards (Amendment) Regulations 2005 (COMAH).
* Ionising Radiations Regulations 2017 (IRR).
* Radiation (Emergency Preparedness and Public Information) Regulations (REPPIR) 2019.
* Nuclear Reactors (Environmental Impact Assessment for Decommissioning (EIADAR)) Regulations 1999 (as amended) (EIADR).

However, a Periodic Safety Review (PSR) produced to comply with LC15 may meet the requirements of the other regulations.

* Requirements for the processes of producing safety cases themselves and aspects relating to the detailed content of safety cases. These are addressed in other ONR Technical Assessment Guides.
* The need for updating safety cases as a result of specific events, such as a change in operation, change in facility life-cycle phase, facility modification, or incidents, which are covered by LC22 Modification or experiment on existing plant. However, these events may influence the time at which a PSR is undertaken such that it coincides with some of these specific events.
* Nuclear security, safeguards and transport requirements.
  1. In this guide, the specific term ‘PSR’ is used to denote typical ten yearly reviews (see paragraph 5.28). More frequent, interim, or continual, reviews should also be undertaken, and these will feed into the ten yearly reviews. These reviews are also covered in this guide.

1. Relationship to licence and other relevant legislation
   1. The regulatory basis for this guide encompasses a number of licence conditions, principally 15(1) – see [1], the purpose of which is to ensure that the licensee makes and implements adequate arrangements for the periodic and systematic review and reassessment of safety cases. Additionally, LC14 (Safety Documentation) requires a licensee to make and implement adequate arrangements for the production of safety cases, whilst LC23 (Operating Rules), specifically 23(1), requires a licensee to produce an adequate safety case in respect of any operation that may affect safety and LC28(1) that the licensee shall make and implement adequate arrangements for the regular and systematic examination, inspection, maintenance and testing of all plant which may affect safety. Further, LC(36) requires that the licensee shall provide and maintain adequate financial and human resources to ensure the safe operation of the licensed site which is also relevant to PSRs.
   2. This document assists in implementing Council Directive 2014/87/Euratom of 8 July 2014 amending Directive 2009/71/Euratom, by highlighting ONR’s regulatory expectations regarding the achievement of the following Article:

*Article 8c - Member States shall ensure that the national framework requires that:*

*(b) the licence holder under the regulatory control of the competent regulatory authority, re-assesses systematically and regularly, at least every 10 years, the safety of the nuclear installation as laid down in Article 6(c). That safety reassessment aims at ensuring compliance with the current design basis and identifies further safety improvements by taking into account ageing issues, operational experience, most recent research results and developments in international standards, using as a reference the objective set in Article 8a.* (as referred to in this TAG and NS-TAST-GD-005 Revision 10[3]).

1. Safety Assessment Principles, WENRA Safety Reference Levels and IAEA Safety Standards addressed

## Safety Assessment Principles

* 1. The SAPs [4] provide a framework to guide regulatory decision-making in the nuclear permissioning process and are supported by TAGs which further aid the decision-making process.
  2. The SAPs are intended to be applied in the assessment of PSRs which should include a comprehensive assessment of the facility’s condition, operating experience, safety case, and management arrangements and culture, looking forward for at least the next ten years and normally, to a lesser extent, the end of life.
  3. The SAPs include a section on the Regulatory Assessment of Safety Cases (paragraphs 79 to 113 of [4]) which has principles on the safety case process (SC.1 and SC.2), safety case characteristics (SC.3 to SC.6), and safety case management (SC.7 and SC.8). However, PSRs are more wide ranging than a restatement of the safety case and instead provide a systematic review of whether the safety case adequately reflects the facility in all situations that may affect safety. This entails reviews that consider all levels of defence in depth (see Principle EKP.3) from the robustness of the facility’s design through to the resilience of its emergency preparedness arrangements. Thus, although these SAPs are not specific to PSRs they set out expectations that apply to safety cases being reviewed or revised as a result of a PSR.
  4. The SAPs document also refers briefly to certain aspects that are directly relevant to PSRs, e.g. facilities built to earlier standards (paragraph 33 of [4]) and ageing (paragraph 35 of [4]). The SAPs also refer to continuous improvement and PSRs, (paragraphs 36 to 38 [4]) and validity of equipment qualification (EMT.4) et al.

## WENRA Safety Reference Levels

* 1. The objective of the Western European Nuclear Regulators’ Association (WENRA) is to develop a common approach to nuclear safety in Europe by comparing national approaches to the application of the International Atomic Energy Agency (IAEA) safety standards. To this end WENRA has developed Safety Reference Levels (SRL) for reactors, decommissioning and waste management and spent fuel storage. The SRL for reactors only apply to existing civil nuclear reactors; the decommissioning SRL apply to all types of nuclear facilities and cover all stages in the lifecycle. The storage SRL apply to facilities where radioactive waste or spent fuel is stored for a significant period of time. The UK is a member of WENRA, has formally signed on to the SRL and, as described in [5], we regard them as good practice that is relevant to the UK nuclear industry and expect them to be followed. PSRs are directly addressed in Issue P of WENRA’s report on reactor SRL [5] Issue I on ageing management which also requires the PSR to confirm whether ageing and wear-out mechanisms have been correctly taken into account. The PSR requirements from WENRA reports on waste and spent fuel storage and decommissioning ([6] and [7]) have been incorporated in this guidance. Table 1 lists the applicable WENRA requirements for nuclear power plant, waste and spent fuel storage and decommissioning, and references the sections in this guidance that pertain to those requirements.

## IAEA Safety Standards

* 1. In addition to the indirect WENRA route, published IAEA guidance directly establishes good practice that is relevant to the UK nuclear industry. General Safety Requirements GSR Part 4 [8] Requirement 24 states that safety assessment shall be periodically reviewed and updated, whilst also observing that safety assessment itself cannot achieve safety. It states that safety can only be achieved if the input assumptions remain valid, the derived limits and conditions are implemented and maintained, and the assessment reflects the facility or activity as it actually is at any point in time.
  2. Facility-specific requirements on PSRs, updated following the Fukushima accident, is provided in SSR-2/2 Safety of Nuclear Power Plants: Commissioning and Operation [9]. It contains a short chapter (Requirement 12) setting out the requirements for a PSR, all of which are included in the WENRA SRLs. Similar facility-specific requirements are also published in SSR-4 on Safety of Nuclear Fuel Cycle Facilities [10] and SSR-3 on the Safety of Research Reactors [11].
  3. SSR2/2 is supported by a Specific Safety Guide (SSG) on PSRs [12] which, in an earlier draft form, informed the development of the WENRA SRLs. The SSG states in paragraph 2.9 that: “The objective of PSR is to determine by means of a comprehensive assessment:
* The adequacy and effectiveness of the arrangements and the structures, systems and components (equipment) that are in place to ensure plant safety until the next PSR or, where appropriate, until the end of planned operation (that is, if the nuclear power plant will cease operation before the next PSR is due);
* The extent to which the plant conforms to current national and/or international safety standards and operating practices;
* Safety improvements and timescales for their implementation;
* The extent to which the safety documentation, including the licensing basis, remains valid.”

* 1. The IAEA SSG on PSR [12] also discusses a means by which the PSR may be conducted through the application of 14 safety factors which can be applied to the facility and licensee’s organisation, at paragraph 2.12. These safety factors have been selected on the basis of international experience and are intended to cover all aspects important to the safety of an operating nuclear power plant. The safety factors are broken down into five groups covering:
* Safety factors relating to the plant
* Safety factors relating to safety analysis
* Safety factors relating to performance and feedback of experience
* Safety factors relating to management
* Safety factors relating to the environment
  1. Licensees should make their own arrangements for conducting PSRs (LC15) however reference to these safety factors may provide a useful prompt when defining the processes for undertaking such reviews.
  2. Although SSG-25 is targeted at nuclear power plants, the essential philosophy and principles employed may be applied to all nuclear facilities. The IAEA safety standards (requirements and safety guides) were the benchmark for the revision of the SAPs in 2006, 2014 and 2020 and are recognised by the ONR as good practice that is relevant to the UK nuclear industry. They should therefore be consulted, where appropriate, by the ONR assessor.

1. Advice to Inspectors

## Purpose of a PSR

* 1. The purpose of a PSR, in line with IAEA guidance [12], is to determine, by means of a comprehensive but proportionate assessment:
* The extent to which the nuclear facility and the safety case conform to good practice that is relevant to the UK nuclear industry.
* The extent to which the safety documentation, including the licensing basis, remains valid and reflects the current plant to ensure that the claims, arguments and evidence are still appropriate and the risks are managed to ALARP, see TAG 005 – ALARP [3].  
  Unlike some other countries with more prescriptive regulatory regimes, the UK did not establish a formal “licensing basis” for many plants currently operating or being decommissioned. However, there are instances where licenses have been granted assuming certain continuing arrangements, for example the provision of supporting skills and facilities for the sharing of dosimetry record keeping arrangements. A PSR should ensure that these arrangements still exist or have been replaced with something that is adequate.
* The adequacy and efficacy of the arrangements and structures, systems and components (SSC) in place to maintain safety until the next PSR or the end of life (which may include decommissioning).
* Safety improvements to be implemented to resolve safety issues.
  1. The term ‘safety case’ is used throughout this document to encompass the totality of the documentation developed by a designer, licensee or duty-holder to demonstrate adequate standards of nuclear safety and radioactive waste management, and any subset of this documentation that is submitted to the ONR.

## Principal Tasks Associated with a PSR

* 1. Primarily a PSR should be of value to the licensee as an integral part of the company’s approach to risk management. It should be documented and structured to be accessible and useable at different management and operational levels within the licensee’s organisation. It should not be aimed solely or specifically at the regulator.
  2. In order to achieve the above, it is vital that the process is owned and led by the safety case owner (typically the facility manager who may delegate this responsibility to a safety case manager). It is also important that facility personnel are involved in the PSR when:
* Determining the scope of current and future operations.
* Reviewing the adequacy of operating instructions and procedures.
* Reviewing the adequacy of maintenance arrangements and spares availability etc.
* Reviewing the adequacy of the list of potential faults and hazards identified in the safety case against extant operations.
* Undertaking reviews and updates of fault analysis and substantiation of claims
* Determining the appropriateness of best practice against facility operations.
* Identifying solutions to shortfalls.
  1. The review should be wide ranging, ‘open minded’ and challenging. It must not be simply an assertion of the safety of extant processes and procedures. It should be a proportionate consideration of where improvements to safety can be made. The review needs to encompass organisational and management systems (people and process) aspects as well as the technical aspects of the facility. This includes so called ‘softer issues’ such as leadership and management for safety which can have a profound effect on safety, as evidenced in the lessons from major events in the nuclear and other sectors.
  2. The principal tasks associated with a PSR can be summarised as follows:
* Systematically review the documentation that constitutes the current safety case in a proportionate manner (i.e. the depth of the review is commensurate with the hazards associated with the plant or facility), to confirm that it remains adequate.
* Where necessary, update and revalidate the safety case as appropriate in light of the above facility reviews, to cover the period of operations up to the next PSR. (It should be noted that significant changes in the scope or type of operations covered by the facility may be planned for the future. These changes will be covered under the LC22 arrangements for modifications as and when they occur.) The extent of such reviews/safety case updates will be dependent upon the deficiencies identified and the extent to which the safety case documentation has been kept up to date, e.g. the inclusion of modifications, dose data and lessons learnt etc., since the last periodic review.
* Systematically review the plant / SSCs important to safety (hazard management strategies/safe operating envelope (SOE)) to confirm their adequacy, efficacy and condition. The review should also cover a forward look for the period up to the next PSR and confirm any known, or identify new, ageing and degradation mechanisms, the availability of manufacturer’s on-going support and availability of spares etc.
* Systematically review arrangements and practices including for leadership and management for safety (L&MfS). This should be a self-critical review of its implementation at facility level, not just a description of the corporate processes and documentation (standards, expectations, procedures, manning levels, retaining knowledge, DAPs/SQEPs etc.). See Annex 1 for further L&MfS guidance.
* Look forward over planned future operation for at least the next ten years, and systematically review the whole of the remaining life of the facility, including post-operational clean-out (POCO) and decommissioning [13].
* Through the reviews provide evidence of the adequacy and efficacy of the arrangements and SSCs that are in place to ensure plant safety, including through the identification of findings, both positive and negative:
* Positive findings (strengths): Where current practices are equivalent to good practice that is relevant to the UK nuclear industry as established in current codes and standards or industry practices, and are found to be adequate and effective.
* Negative findings (deviations or shortfalls): Where current practices are not of a standard equivalent to current codes and standards or industry practices, or are inconsistent with operational documentation for the plant or operating procedures, or do not meet legal requirements or expectations.
* Identify temporary short term improvements where necessary for continues operation, and permanent long term safety improvements to address deviations and shortfalls and show that these will be implemented so far as is reasonably practicable, in a timely manner (see paragraphs 5.48 to 5.56). Once identified, the improvements should be integrated into a risk prioritised programme for the facility that should include on-going modifications.
* The PSR should arrive at a judgement of the facility’s suitability for continued safe operation for the next review period (typically 10 years [2]), on the basis of a balanced view of the findings from the PSR reviews.
  1. When undertaking the above, use can be made of information gathered over the previous review period, on a continuous basis, where relevant e.g. maintenance data, health physics data, incident data etc.

## Scope of a PSR

### Scope: General aspects

* 1. The scope and structure of a PSR are a matter for the licensee to determine, although they should meet ONR’s expectations as set out in this guide, and the expectations of international good practice (particularly [12]) unless the licensee can justify an alternative approach. The scope and structure should be defined clearly prior to the review and should be shared with ONR to confirm that they meet regulatory expectations.
  2. The scope of a PSR should meet the purpose and principal expectations set out above. It needs to extend beyond an individual facility to recognise the influence of company-wide or corporate policies, standards, processes and practices (for example the company nuclear safety policy, safety culture principles, leadership and management for safety standards and practices, company-wide learning activities and improvement plans e.g. decommissioning programmes, procurement etc.).
  3. The PSR should encompass the following in a proportionate manner commensurate with the risks:
* The individual and cumulative effect of changes to relevant standards, regulations, criteria and methodologies since the last review to ensure they have been appropriately addressed (including possible changes in the circumstances or ranges for which they have been validated).
* Changes in technology (e.g. research findings, inspection techniques, modernising of equipment) or in knowledge (e.g. operational experience, organisational learning).
* Changes in the organisational structure and resources and their cumulative impact (e.g. reduction in resources, facility knowledge, leadership etc.).
* Changes in the arrangements and practices for leadership and management for safety.
* Modifications to the facility, its equipment or mode of operation.
* Reliability, maintenance, monitoring and surveillance data from both the plant and similar relevant operations worldwide, in order to identify any ageing or degradation processes or obsolescence issues that may affect safety significant structures, systems and components.
* Recommendations from previous reviews (including PSRs) yet to be implemented. In these instances, there would also need to be very strong ALARP arguments for why this is the case. [The project inspector may need to take further action in these instances, as noted in the Section on inadequate submissions].

The PSR should also:

* Identify the relevant modern standards and good practices against which the review has been undertaken.
* Identify the cut-off date(s) beyond which changes to codes and standards and new information was not considered.
* Include a listing and explanation of improvements identified during the review, categorised in terms of safety importance.
* Include the programme of work to implement reasonably practicable improvements to enhance safety.
* Identify when the next PSR is due. There is a regulatory expectation that a PSR will be produced every ten years; however, as a result of the review the licensee may decide that one is required sooner. In exceptional cases, the licensee may be able to justify a longer period between PSRs (see paragraphs 5.32 to 5.39).
  1. The above lists are not exhaustive and other aspects may need to be considered. For example, a list of topics recommended for PSRs of nuclear power plants is given in [8] and for decommissioning facilities in [7] (Section D-75). The Safety Case Forum also produces industry guidance on behalf of the Safety Directors’ Forum[[1]](#footnote-1), much of which seeks to address issues with safety case production. Inspectors should be aware of this guidance, which is published on the Safety Directors’ Forum webpages. ONR expectations for leadership and management for safety aspects to be covered in a PSR are given in Annex 1 of this guide. The totality of the areas covered in a PSR should be consistent with the underlying objectives of the PSR and the nature of the facility and its operations. TAG 051 [14] – The Purpose, Scope and Content of Safety Cases also provides further information on safety cases.
  2. The PSR should include a full and systematic review of the safety case, to ensure that the claims being placed on the facility can continue to be delivered, rather than a re-write of the case (although the latter could be an outcome from the PSR). Since the scope of an adequate safety case will be proportionate to the hazards and risks from the facility, the PSR will necessarily also be proportionate to these same hazards, risks and the extent of any changes to the facility. ONR’s assessment of PSRs should take account of the risks and hazards when determining the extent of the assessment work. If the project inspector deems the PSR to be inadequate e.g. in terms of the breadth and depth of the assessment, or if an appropriate action plan for dealing with shortfalls has not be identified, then there may be a need to withhold written confirmation of the acceptability of the PSR until they are satisfied that an adequate submission has been made (see paragraphs 5.75 and 5.76).

### Scope: Detailed aspects

* 1. In considering ageing, degradation and obsolescence processes (hereafter referred to as “ageing”), the PSR should determine whether a systematic and effective ageing management programme is in place; whether adequate arrangements have been made to fulfil the required safety functions during future plant operation; and whether there are any features that would limit plant life. Both the technical aspects of ageing management (e.g. ageing management methodology; the extent of understanding of relevant age-related degradation mechanisms; any SSC specific acceptance criteria, operating guidelines aimed at controlling the rate of ageing degradation, and ageing detection and mitigation methods; and the actual condition of SSCs) and the management arrangements required to deliver them (e.g. policies, procedures, performance indicators, staffing, resources and record keeping) should be reviewed. The PSR should highlight any ageing features that require attention before the next PSR e.g. life-limiting factors, obsolescence etc. This information can be drawn from existing information where available such as plant maintenance records, procurement data etc. which may be collected on a continuous basis. The licensee should then ensure that these are addressed during appropriate interim reviews.
  2. The licensee’s PSR arrangements should ensure, by methods such as facility walk-downs that the facility configuration and condition reflected in the safety case reflects the actual facility state and that it can deliver the required safety functions (SAPs SC.4, EQU.1). The review should use up to date, systematic and documented methodologies, taking into account deterministic and, where relevant, probabilistic assessments. Consideration should also be given to all modes of operation permitted within the safety case, such as those arising during maintenance, refuelling and shutdown/start-up activities, to determine whether there is any potential for increased or unacceptable levels of risk arising from them. The adequacy of arrangements for reviewing operating instructions, warning notices, training programmes, and other aspects that underpin safe operation should also be considered.
  3. The arrangements should also ensure that an appropriate blend of facility specific engineering, safety case specialists, and operational expertise is brought together to carry out the PSR. The arrangements should make provision for adequate independent review of the work, both in terms of the documentation produced and the processes applied e.g. independent verification of engineering substantiation reports, peer review of safety case documentation etc., noting that this should take place throughout the PSR process and not just at the back-end. In addition, the licensee should provide for the identification of clear lines of management responsibility, including a safety case owner and person(s) responsible for overseeing the PSR and for owning the findings and improvement programme.
  4. The review of the safety case should proportionately consider all safety analysis of fault conditions, including the processes and methods used and associated output including (this list is not exhaustive);
* The adequacy of the fault identification and fault schedule taking account of the current understanding of the state of the plant e.g. ageing factors, operating beyond its original design life etc. which may introduce new faults
* The adequacy and scope of analyses of identified faults considered through design basis analysis, probabilistic safety analysis and severe accident analysis techniques e.g. are these applying the latest tools and methods, computer codes etc.
* The demonstrations that risks are as low as reasonably practicable (ALARP) need to be revisited and reviewed against current good practice that is relevant to the operations to ascertain whether or not they remain valid such that no further improvements are required.
* The SOE and operating rules need to be reviewed to reflect any changes in the hazard analysis and plant operating experience
  1. Specific Safety Guide No. SSG‑25 [12] provides further information within the discussion on safety factors relating to safety analysis in addition to the ONR TAGs which provided further details on the expectations for a modern standard hazard analysis.
  2. For multi-facility sites, the scope of the PSR will need to take into account site-wide services (e.g. electrical services, emergency services) and any other matters important for the safety of facilities that are not included in the facility PSRs (e.g. the safety impact of one facility on another). This type of ‘Site-wide PSR’ could be combined with the concept of a Corporate PSR to cover all aspects that are broader than an individual facility. Site-wide topics to be addressed include:
* Dependencies on common services and other facilities.
* A demonstration that all operations which may affect safety on the site are addressed by a safety case.
* Radiological protection (see Annex 3).
* Emergency planning.
* Minimum manning.
* Radioactive waste and environmental impact.
* Overall hazards and risks from the site, particularly from those hazards which can impact multiple facilities on the site at the same time, or have a ‘knock-on’ impact, for example external hazards and fire.
  1. The PSR should review and justify the continuing adequacy of the licensee's organisation, including the control of changes to the organisational structure or resources available to it which may affect safety. Further guidance is given in [14], [15] and [16]. With the many organisational changes that have taken place in the nuclear industry in recent years, and which are likely to continue, it is important that the PSR covers areas such as technical support capability (notably retention of core competencies, Design Authority and ‘intelligent customer’ capability), staffing levels and capabilities, succession planning, control of contractors, and learning from experience (incidents and safety performance). The PSR should consider if the licensee's organisational structure and resources available to it are adequate for its current and future needs, including benchmarking with other organisations where appropriate. This could lead to a re-definition of the licensee's ‘Baseline’ [16].
  2. For licensees with several sites or facilities, one way to achieve the appropriate coverage would be to produce a ‘Corporate PSR’ to review the corporate/company- wide aspects (including areas highlighted in Annex 1). The site or facility specific PSRs could then refer to and draw upon the information in the Corporate PSR and review how well the company policies, standards etc. have been implemented at the site or facility in question.
  3. Where a facility provides a safety function that cannot be provided by an alternative means, the forward review should include consideration of the time which may be needed to design, construct and commission, or to procure a replacement facility or equipment, should the original be found to be unserviceable at some point in the future, i.e. there must be no interruption in safety function. This applies particularly to radioactive waste stores, and to other facilities in which the hazard cannot be simply removed by shutting them down [17]. For stores containing bulk quantities of nuclear matter, the PSR needs to consider the entire period up to the end of retrieval operations. This is particularly important if the nuclear matter is chemically reactive, heat generating, degrading or could leak to the environment. This review may need to consider other factors such as the licensees overall site programme and how the facility fits into this e.g. long term requirements for the safety function provided by the facility, future programme requirements, the availability of other facilities on the site that could provide the safety function etc.
  4. Where appropriate, the PSR should consider the need for, and availability of, appropriate storage facilities for radioactive waste or spent fuel arising from the facility and the identification of a suitable disposal route. This may include a consideration well beyond the normal ten-year window, and would need to take into account the longevity of any storage proposal and the potential need for additional storage capacity and associated treatment facilities. For such facilities that cannot be shut down the PSR should consider the safety issues that may arise over their total projected lifetime, including any associated facilities.
  5. Coverage of decommissioning aspects of PSRs should grow in scope and detail as a facility ages and approaches the end of its normal operating life. Early PSRs should concentrate on the technical strategy and outline plans for decommissioning [13], making use of the design provisions. Later on, as decommissioning becomes imminent, the PSR should address matters such as the detailed decommissioning plan, its integration with waste management strategies and the decommissioning safety management system. See Annex 2 for further guidance.
  6. There may be occasions where a PSR demonstrates that the licensee cannot in fact provide an adequate safety case to cover the whole of the subsequent period of operation until the end of life or the next review. This might, for example, occur because of limited knowledge of ageing and degradation mechanisms as plant reach ages beyond those with which the industry as a whole has direct experience. In these cases the licensee must have in place a longer-term strategy for the management of safety until the guaranteed shut down date (see 5.56(i)) or the next PSR (whichever is sooner). That strategy should include:
* A demonstration that continued operation is appropriate and that risks are ALARP i.e. that failure to meet the affected limit or condition would not present an unacceptable risk, and that all reasonably practicable options have been implemented to prevent or mitigate that risk. As well as engineering or procedural enhancements, this might include operation in modes that reduce risk. It is expected that such a justification would be underpinned by thorough and systematic optioneering.
* A robust process for managing (and decreasing) uncertainty and risk. This will include (but not necessarily be limited to) ongoing monitoring and review activities.
* Any additional research that is necessary.
* Conservative contingency planning.

## Periodicity of PSRs

### Periodicity: General

* 1. On the basis of international experience, it is reasonable to perform a PSR typically ten years after the start of facility operation (usually marked by the issue of an operational safety case which will baseline the facility, plant and equipment against modern standards at that point in time) and then to undertake subsequent PSRs at roughly ten year intervals (but see paragraph 5.31).
  2. Ten years is considered to be an appropriate interval in view of the likelihood, within this period, of the following:
* Changes in national and international safety standards, operating practices, technology, underlying scientific knowledge or analytical techniques.
* The potential for the cumulative effects of plant modifications to adversely affect safety or the accessibility and usability of the safety documentation.
* Identification of significant ageing effects or trends.
* Accumulation of relevant operating experience and organisational learning.
* Changes in the way the facility is, or will be, operated.
* Changes in leadership, management structures and practices in the facility and/or licensee’s organisation.
* Changes in organisational structure, staffing levels or in the experience of staff.
* Changes in the natural, industrial, or demographic environment around the facility.
  1. The licensee is responsible for determining when PSRs should be undertaken, subject to the general constraint that the period between PSRs should be typically no more than ten years (unless otherwise agreed with ONR). LC15 requires the licensee to produce PSRs but the ten year period is not an explicit statutory requirement. In addition, ONR may specify an earlier PSR submission date using LC15(4) in the interest of safety (as stated in para 5.60). An example of where this may be relevant is touched on in para 5.24, referring to circumstances where there are uncertainties relating to the adequacy of the safety case for the subsequent review period.
  2. In the absence of any other requirements the first PSR of a new facility should be completed within ten years of fuel being loaded into a civil reactor, or within ten years of the start of active commissioning for a non-reactor plant and then every ten years thereafter (see para 5.25).
  3. Licensees may choose to re-write their safety case for reasons unrelated to PSR. For example, sites that are no longer operational may produce a new safety case once a major hazard reduction milestone (for example, completion of defuelling, or when a particular activity starts or ends such as refuelling a submarine) has been reached. Providing the work done in producing the new safety case reviews all aspects necessary for a PSR and is appropriately documented e.g. LFMS, look ahead et al, ONR may consider the revised safety case acceptable substitute for a PSR. The next PSR would then be due ten years from when the revised safety case is formally adopted.
  4. A licensee may also produce a PSR well before the due date. This may arise, for example:
* To align with a major reactor inspection programme
* Where ageing mechanisms demand more frequent review.
* Where operational experience or significant changes in standards indicate that an earlier review may be prudent e.g. If there are known degradation mechanisms that need to be reviewed within the ten year period
* A significant change in operation occurs, e.g. decommissioning, submarine refurbishment/reactor re-fueling.
  1. A PSR that is produced early should still address the principal requirements identified previously in Section 4 before the ten-year ‘clock’ is reset.

### Periodicity: Continual or Interim Reviews

* 1. The production of a PSR need not necessarily be a major undertaking once every ten years. An alternative approach is to place more emphasis on continual or interim reviews of safety and/or data gathering, encompassing the principal requirements and scope of PSRs. This has the advantage of identifying potential issues earlier and of fewer major issues emerging at the ten-yearly reviews. It is also has the potential to be less resource intensive at any given time and may provide the licensee with more flexibility in the management of resources and other operational programme requirements.
  2. IAEA SSG-25 [12] notes that a continuous review programme can, if applied with appropriate scope, frequency, depth and rigour, achieve the same outcomes as the process recommended for a ten year review. In these instances, the licensee should allow safety to be improved on a continuous basis and avoid the need to implement concurrently a large programme of corrective actions. In these instances it is important that the ONR inspector ensures that all areas of the plant/facility are still reviewed, proportionately, on a regular basis not exceeding ten years.
  3. A more continuous review process does not remove the requirement for a ten-yearly PSR. However, that PSR could take credit as appropriate for continual or interim reviews that have been undertaken, and provide a summary of the main findings of these reviews, noting that such information would need to be shared with the ONR inspector on a more frequent basis to ensure it is valid. The PSR would also have to include any additional work necessary to ensure the full requirements of a PSR have been met. In particular, the PSR must demonstrate safety for the next ten years, something that individual reviews taken in isolation are unlikely to be able to do. Again, the ONR inspector needs to satisfy themselves that where data/reviews are undertaken more frequently, the information gathered is appropriate for the less frequent reviews.
  4. The totality of continual, interim and ten-yearly reviews should encompass all the relevant topics highlighted in earlier sections of this guide on the purpose, requirements and scope of a PSR. It is therefore important that the continual or interim reviews are adequately scoped, planned, resourced, conducted and recorded to ensure that appropriate benefit can be taken from them during the ten-year PSR.
  5. Where licensees elect to follow a process of continual or interim reviews, they need to ensure that identified improvements are implemented within appropriate timescales and are not delayed unnecessarily (e.g. until the production of the ten-yearly PSR).
  6. Systems or components whose behaviour or nature may undergo significant change in the interval between major reviews should be addressed by interim reviews. One possible outcome of an interim review is that the next scheduled PSR date is brought forward.
  7. Regardless of the licensee’s preferred option for meeting the regulatory expectations of a ten-yearly PSR, the arrangements under LC15 should include interim reviews to ensure that the cumulative impact of all modifications and changes has been considered so that the safety case remains valid and up to date. Thus, an important outcome from continual or interim reviews is the consideration of the need to update the facility or site safety case and other relevant documentation (e.g. procedures, organisational baseline) to reflect changes in the facility. If updates are not incorporated promptly into the extant safety case, other measures may be needed to enhance the accessibility and usability of the safety case, particularly in any areas where there have been numerous changes that make the design basis difficult to identify.
  8. As a minimum, interim reviews should take into account the number and safety significance of modifications to the facility or safety case and changes to the organisation since the previous review. Interim reviews should also consider operating experience and the overall impact of incidents, events and operational changes. Components whose behaviour or nature may undergo significant change in the interval between major reviews should be encompassed by interim reviews. Interim reviews would normally be expected every one to three years, depending on the nature of the facility. Within this time span, the period could be flexible if account is taken of the number of changes that occur.

### Phases of Operation

* 1. The timing of a PSR for facilities about to be permanently shut down facilities should normally be undertaken to coincide with the production of the re-baselined safety cases written to support any significant changes in the mode of operations that may occur. Examples of changes in mode include:
* The end of power operation for a reactor.
* The commencement of decommissioning operations at completion of final defuelling.
* At the transition to a care and maintenance regime, e.g. safestore, once all reasonably practicable decommissioning activities have been undertaken.
* Re-fuelling and/or refurbishment of a nuclear submarine
  1. The production of a re-baselined safety case following such a change in mode may obviate the need for a full-scope PSR. Instead, PSRs produced in conjunction with a new safety case should be limited to a review of matters not addressed directly within the new safety case (e.g. operational experience from relevant events and incidents, condition of plant and efficacy of arrangements, LMFS). Such PSRs would be carried out irrespective of whether the ten years has elapsed since the previous PSR. If changes in the mode of operations are anticipated to occur within a few years after the ten year period, then ONR should consider, in consultation with the licensee, whether a review at ten years remains appropriate; it may be acceptable to delay the PSR so that it can be carried out in conjunction with development of a revised safety case. Such situations need to be considered on an individual basis taking into account relevant factors, including: degradation that might occur in the additional period; the approach adopted by the licensee with regard to continual or interim reviews; and the extent of the licensee’s commitment to the timescale for the change in operational mode.
  2. If a PSR is linked to the production of a re-baselined safety case it should not simply provide a summary of the re-baselined safety case. The documents should instead be complementary so that the sum of the new safety case and the review meet all relevant safety case and PSR requirements.
  3. Provided the re-baselined safety case plus the associated review fulfils all the requirements of a PSR, e.g. contains appropriate elements of a forward and back review, then the next PSR will not be required until ten years after the adoption of the re-baselined safety case.

## Outputs from a PSR

**Output: General**

* 1. The outputs from a PSR should be summarised in an overview report. This report should be understandable to the key users of the PSR i.e. those interacting directly with the plant and the Company Directors/Senior Managers, with links to more detailed documents as necessary.
  2. The overview report should arrive at a judgement of the facility’s suitability for continued safe operation for the following review period (usually ten years) on the basis of a balanced view of the findings from the PSR reviews. Where a continuous review process has been used its adequacy should be assessed in the report to confirm it has provided the appropriate information to provide a suitable review and look forward for all areas of the facility and its associated safety case. This judgement should take account of the safety improvements considered necessary (which may relate to the plant, safety case, arrangements or to the operating organisation) together with any positive findings (strengths) identified in the reviews. The overview report should evaluate the impact on safety based on the findings from all the reviews and so should be performed after completion of all the individual reviews.
  3. The total effect of the negative findings, safety improvements and positive findings (strengths) identified in the PSR should be examined using deterministic methods to ensure that the overall risks associated with continued operation of the plant remain as low as reasonably practical (ALARP).
  4. The risks associated with negative findings should be assessed and an appropriate justification for continued operation should be provided. This justification should address operations both in the short term prior to the implementation of identified safety improvements and in the long term if the assessment concludes that addressing some of the negative findings is not reasonable and practicable. Some engineered solutions may take time to implement and require interim measures to be put in place e.g. procedural safety measures, so that operations can continue.

**Output: Shortfalls**

* 1. The PSR should identify any shortfalls against modern standards and good practices, with a programme to implement all reasonably practicable improvements in the facility and its operations, including revisions to the documented safety case, to ensure that risks to the public and workers will be ALARP. The licensee should develop and then execute this programme in a timely manner. The implementation work should be carried out as an ongoing process in accordance, where necessary, with a strategy for identifying facility priorities and in a manner that ensures the safety case remains 'live' throughout.
  2. In addition to identifying individual shortfalls, the PSR should include an assessment of their combined effects and overall impact i.e. common root causes such as lack of maintenance, ageing, obsolescence etc. This assessment should also consider potential interfaces between shortfalls and the identification of solutions that may improve multiple systems e.g. electrical supply upgrades, improved fire protection etc. This should result in a more integrated improvement programme and the prioritising of solutions that have the highest impact on risk reduction.
  3. Where the PSR identifies an issue that significantly compromises the safety of the facility, the licensee should take immediate action to ensure that its operations remain in compliance with an adequate safety case (LC23(1) and LC23(3)). This may mean halting operations until an appropriate safety case justification is in place, or a safety improvement implemented. In the interests of urgency, such improvements will normally be managed outside the wider PSR improvement programme.
  4. Modifications should be progressed through the arrangements in support of LC22 and should not be delayed until ONR reaches a view on the adequacy of the PSR. The justification for any significant modification will be submitted to ONR for consideration under LC22 arrangements. There is also likely to have been early discussion on the proposals to rectify significant shortfalls identified by the PSR involving the licensee and ONR as part of normal regulatory engagement.
  5. The intent should be to implement all improvements before the PSR 'Decision Date' (i.e. Submission Date + 1 year; see [Table 2](#Table2)), unless alternative arrangements have been agreed with the ONR. In cases where this is not reasonably practicable, the improvements should be completed in a timely manner within a two year period after the Decision Date, unless the licensee can make a strong case for going beyond this period such as long lead times for the design and procurement of plant and equipment. However, in such cases, the site inspector should ensure that continued realistic progress is being made to close out these shortfalls in a timely manner. The arrangements should also ensure that an effective control and monitoring process is in place to provide confidence that satisfactory close out of all PSR-related work will be achieved within the programmed dates
  6. The licensee should set out the reasoning behind the proposed improvement programme and completion timescales, in particular for work that extends beyond the Decision Date. In applying the test of 'reasonable practicability' the extent of major improvements and options for implementation may be taken into account (e.g. undertake during planned major outage periods).
  7. Reasonable practicability arguments for not implementing improvements should follow ONR’s ALARP guidance [3]. The supporting justification should take into account the actual condition of the facility, equipment, activity etc. at the time of the PSR submission and its potential deterioration up to the next PSR. The reasonable practicability arguments might include:

i) that the benefit would only be applicable during normal operation; the time to implement would extend beyond final shutdown; and the shutdown date has been guaranteed, e.g. in a letter to ONR (without such a guarantee a period of at least a further ten years of normal operation should be assumed in the ALARP argument);

ii) that it is physically impossible or impracticable to modify the facility so as to achieve compliance with modern standards; or

iii) that the sacrifice from bringing the facility up to modern standards (e.g. in terms of time, trouble or cost) would be grossly disproportionate to the safety benefit gained.

* 1. Where ONR identifies further work to be undertaken over and above that identified by the licensee, such work should generally be completed within two years of the PSR Decision Date. Exceptions include:

i) requirements relating to an agreed ongoing activity (e.g. condition monitoring) which can be incorporated into normal regulatory processes, e.g. start-up meetings following periodic shutdowns, or routine site review meetings; and

ii) requirements that result in major facility modifications or major analytical work, which may not be capable of completion within the stated period.

* 1. The licensee, in discussion with ONR, should take into account not only the relative significance of the PSR shortfalls but also other (non-PSR) nuclear safety related work and improvements. This could include important work the licensee has to complete to meet other commitments to ONR such as hazard reduction on sites that are being decommissioned. (Note: this does not mean the licensee can ignore the indicative timescales in this guide for completing PSR improvements, but the licensee and ONR need to consider overall priorities for nuclear safety).

## Licensee’s PSR Production Programme

* 1. Each licensee’s LC15 arrangements should require the submission of a programme of PSRs for its sites and facilities to ONR for consideration. The timing of PSRs is the licensee’s prerogative, subject to the constraints highlighted earlier.
  2. Prior to undertaking the work, it is advisable for a licensee to have preliminary discussions with ONR and/or the licensee’s internal regulator on the scope of a PSR, including the modern standards to be used for benchmarking. These early discussions do not prejudice ONR’s assessment of the completed reviews but help to ensure that any fundamental issues over the basis of the PSR are identified at an early stage.
  3. The licensee should have arrangements for implementing any new or revised safety case resulting from the PSR, and should ensure, in line with paragraphs 5.57 – 5.61, that all significant changes are implemented according to any timescales agreed with ONR. In normal circumstances where the safety case changes, the change itself should be carried out and categorised appropriately under the modification arrangements required by LC22.
  4. Normally, the licensee's arrangements should make provision for submission of the PSR twelve months before the date when ONR anticipates reaching a view on the adequacy of the PSR, usually referred to as the ‘Decision Date’. The PSR submission date will normally be decided by the licensee although ONR may specify a different date using LC15(4) in the interest of safety. An indicative programme for production of a PSR submission is illustrated in [Table 2](#Table2).
  5. Licensees’ arrangements should include the provision for ONR to set formal engagement points for ONR to monitor progress if necessary in the interests of safety. When a licensee’s activities are delayed, the licensee should provide ONR with an appropriately robust and detailed justification so that ONR can intervene appropriately. Failure to submit a PSR within the time period specified in the licensee’s arrangements could result in regulatory action in accordance with the EMM [18].

### Special Arrangements for Multi-Facility Sites

* 1. Different arrangements may be made for multi-facility sites, where the licensee chooses to undertake PSRs for individual or groups of facilities at different points in time (for example, to spread the work load). In such cases, the licensee will need to define a rolling programme of PSRs, ensuring that all reviews are undertaken within a ten year period. This programme should be regularly reviewed and submitted to ONR, with proposed PSR submission dates.
  2. The Site-wide or Corporate PSR (see paragraphs 5.23 and 5.24) should demonstrate the adequacy of the overall programme of reviews. It should also summarise the outcomes from individual facility PSRs undertaken since the last site-wide PSR.

### Interim or Continual Reviews

* 1. If the licensee chooses to conduct interim reviews as described in paragraph 5.38 then the scope and timing of those reviews and the overall programme should be set out and discussed with ONR. Similarly, if the licensee undertakes continual reviews, their purpose, scope and nature should be defined and discussed with ONR. For interim or continual reviews, the licensee should also take into account the need for, and timing of, a more stand-back ten-yearly PSR. It is also important that continual reviews look at all areas of the facility in a proportionate manner at least once every ten years see paragraph 5.25.

## ONR's Assessment Programme

## Adequate Submission:

* 1. ONR’s response to a PSR will vary proportionally on a case-by-case basis depending on a number of different considerations, e.g. size of hazard and risk; extent and nature of changes to a facility or its operations since previous review. The ONR response may be to do no assessment; undertake a light touch inspection with a team of inspectors (similar to a readiness review); a detailed assessment; or something in between the two e.g. the ONR project inspector forms their view on the adequacy of the PSR using their knowledge of the facility and its operations over the review period. The basis of the ONR assessment should be determined at the start of the PSR process through consultation with the licensee to ensure that both parties understand what the formal ONR submission and assessment will entail. If an assessment or inspection is to be undertaken then the ONR project inspector for the PSR submission should establish a programme for its assessment, with the aim of producing the collated findings to the licensee within a reasonable period, typically three months, prior to the ‘Decision Date’ (see Table 2)
  2. ONR should have had discussions with the licensee on the scope of the PSR at an early stage in the programme, for the reasons set out in paragraph 5.58. ONR should take care not to influence the licensee to structure the PSR to make ONR’s assessment work easier; the PSR needs to be structured to be of most use to the licensee, in accordance with their arrangements.
  3. If the licensee undertakes interim reviews, the scope of each planned review and the overall programme should be discussed with ONR. A consensus can then be reached with the licensee on what the ONR inspector will formally request for assessment. Similarly, if the licensee undertakes continual reviews, ONR should have an understanding of their scope and nature and discuss what might need to be submitted in the interim periods between the 10 yearly reviews. The need for more stand-back ten-yearly PSRs will still apply and ONR should seek confirmation that the combined scope of all the reviews meets the expectations set out in this guide.
  4. For a full ten-yearly PSR, the documented PSR findings and associated programme of work to implement any improvements should form the basis of a formal submission to ONR. This submission is distinct from a revised safety case (generally covered under LC22 modification or experiment on existing plant) that could be one of the outputs from the review. The work done during the PSR should also be reported, including the procedures applied.
  5. In carrying out the assessment of the PSR submission, the ONR project inspector and specialist inspectors should bear in mind a distinction between queries or issues that will arise during the assessment process and the need to have final PSR ‘findings’. The ONR inspectors may wish to gain familiarity with the facility prior to the formal PSR submission, so that they are able to put the findings and anticipated solutions into context. Queries and issues should be addressed and, if possible, resolved as part of ONR’s assessment of the PSR submission. The outcome should culminate in specific and clearly defined ‘findings’, as necessary, where ONR considers the licensee needs to undertake more work and/or deliver improvements as part of the PSR programme.
  6. The ONR project inspector, working with specialist and site inspectors, should maintain an overview of issues and any resultant findings. Where appropriate, issues and/or findings should be collated into fewer but more effective PSR actions on the licensee. Findings from the PSR should be recorded and tracked on the regulatory issues database [19].
  7. On completion of the assessment, a project assessment report should be produced to document ONR’s view on the adequacy of the PSR. In line with ONR’s openness and transparency policy, this project assessment report would be published on ONR’s website. For multi-facility sites ONR may issue a single public report of its PSR programme findings, triggered by the Site-wide PSR or Corporate submission, rather than for each individual facility. Public reports may additionally be produced in response to facilities of particular significance.
  8. ONR will either confirm with the licensee a favourable decision on the adequacy of the review, or will set out specific actions to be taken. Where the PSR is deemed adequate, there is still a need for any recommendations or shortfalls resulting from the review to be addressed by the licensee in a timely manner. These need to be agreed with the site inspector along with the timescales for their close out so that they can be reviewed by the site inspector at an appropriate point.
  9. ONR’s PSR findings and actions should be prioritised, in discussion with the licensee. All actions should then be recorded and tracked using the regulatory issues database [19]. This should take into account not only the relative significance of the findings but also other (non-PSR) nuclear safety related work and improvements that the licensee is undertaking (see paragraph 5.58).
  10. Regardless of the decision taken or the timescale for required improvements or activities, the Decision Date for the next PSR should normally be set at no more than ten years from the current PSR Decision Date.

## Inadequate Submission:

* 1. There may be instances where the PSR submission falls short of ONR expectations and further work may be required by the licensee either on the PSR process itself or the appropriateness and timescales associated with remedial work to rectify and identified shortfalls.
  2. Depending on the circumstances, specific regulatory powers can be used to ensure that those actions are carried out; for example, regulatory powers might be used to: direct the licensee to carry out a further review in accordance with LC15(4); direct the licensee to cease operation in accordance with LC31(1); or require the licensee to undertake specific improvements or carry out other activities, such as preparing a forward improvement programme, using an Improvement Notice.

1. References

1 Licence condition handbook. Office for Nuclear Regulation. February 2017. <http://www.onr.org.uk/documents/licence-condition-handbook.pdf>

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4 *Safety Assessment Principles for Nuclear Facilities.* 2014 Edition Revision 1. ONR. 2020.

5 *Western European Nuclear Regulators’ Association.* *WENRA Safety Reference Levels for Existing Reactors – Update in relation to lessons learned from TEPCO Fukushima Dai-Ichi accident. 24th September 2014. WENRA reference levels. September 2014.*

6 *Waste and Spent Fuel Pool Storage Safety Reference Levels.* WENRA harmonized storage reference levels report. WENRA Working Group on Waste and Decommissioning (WGWD) Western European Nuclear Regulators’ Association. Version 2.2, April 2014.

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*8 Safety Analysis for Facilities and Activities: Commissioning and Operation.* IAEA Specific Safety Requirements No. GSR-4 Part 1 (Rev. 1). International Atomic Energy Agency (IAEA). 2016. [www.iaea.org](http://www.iaea.org).

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13 *ONR How2 Business Management System. Decommissioning.* NS-TAST-GD-026 Revision 5. ONR. September 2019.

14 *ONR How2 Business Management System.The Purpose Scope, and Content of a Safety Case. NS-TAST-GD-051 Revision 6. ONR. December 2019.*

<http://www.onr.org.uk/operational/tech_asst_guides/index.htm>

15 *Successful health and safety management.* HSG65 (Second edition). HSE Books 1997. ISBN 0 7176 1276 7.

16 *ONR How2 Business Management System. Technical Assessment Guide – Function and Content of the Nuclear Baseline.* NS-TAST-GD-065, Revision 3. August 2018. <http://www.onr.org.uk/operational/tech_asst_guides/index.htm>

17 *ONR How2 Business Management System. Safety Aspect Specific to storage of Spent Nuclear Fuel.* NS-TAST-GD-081 Revision 2. ONR. June 2019. <http://www.onr.org.uk/operational/tech_asst_guides/index.htm>

18 ONR How2 Business Management System. Enforcement. ONR-ENF-GD-006, Revision 2. ONR. August 2019.

*19 ONR How2 Business Management System. Management of Regulatory Issues – Guidance. ONR-RI-GD-003 Revision 4 August 2017.*

20 *ONR How2 Business Management System. Function and Content of a Safety Management Prospectus.* NS-TAST-GD-072 Revision 3. ONR. July 2018. <http://www.onr.org.uk/operational/tech_asst_guides/index.htm>

21 Application of the Management System for Facilities and Activities. IAEA Safety Standards. Safety Guide No. GS-G-3.1, International Atomic Energy Agency (IAEA). 2006. [www.iaea.org](http://www.iaea.org).

*22* *ONR How2 Business Management System. Management of Radioactive Materials and Radioactive Waste on Nuclear Licensed Sites.* NS*-*TAST-GD-024, Revision 6. September 2019.  
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*24 ONR How2 Business Management System. Radiological Protection, NS-TAST-GD-038 Revision 8, November 2017.* [*http://www.onr.org.uk/operational/tech\_asst\_guides/index.htm*](http://www.onr.org.uk/operational/tech_asst_guides/index.htm)

*25* Ionising Radiations Regulations 2017/1075 (IRR17) Approved Code of Practice and Guidance, L121, Second Edition 2018.

Note:ONR staff should access the above internal ONR references via the How2 Business Management System.

1. Glossary and Abbreviations

|  |  |
| --- | --- |
| ALARP | As low as reasonably practicable |
| C&M | Care and maintenance |
| COMAH | Control of Major Accident Hazards |
| EMM | Enforcement Management Model |
| EIADAR | Environmental Impact Assessment for Decommissioning 1999 (as amended) |
| EIMT | Examination, Inspection, Maintenance and Testing |
| HAZAN | Hazard Analysis |
| HAZID | Hazard Identification |
| HSE | Health and Safety Executive |
| IAEA | International Atomic Energy Agency |
| IRR | Ionising Radiation Regulations 2017 |
| L&MfS | Leadership and Management for Safety |
| LC | Licence Condition |
| ONR | Office for Nuclear Regulation |
| NIA | Nuclear Installations Act 1965 |
| POCO | Post-operational Clear-out |
| PSR | Periodic Safety Review |
| REPPIR | Radiation Emergency Preparedness and Public Information Regulations 2019 |
| SAP | Safety Assessment Principle(s) (ONR) |
| SOE | Safe Operating Envelope |
| SD | (PSR) Submission Date |
| SRL | Safety Reference Level(s) |
| SSC | Structures, Systems and Component(s) |
| SSG | Specific Safety Guide |
| SQEP | Suitability Qualified and Experience Person |
| TAG | Technical Assessment Guide(s) |
| WENRA | Western European Nuclear Regulators’ Association |
| WGWD | WENRA Group on Waste and Decommissioning |

Annex 1: Expectations for the Coverage of Leadership and Management for Safety Aspects in PSR

1. Major events worldwide in the nuclear and other sectors continually highlight the importance of leadership, management for safety and culture. Weaknesses or shortfalls can and do lead to major events in experienced organisations with established management systems. Investigations often reveal that weaknesses and warning signs existed for some time before the events but were not highlighted or not considered significant. The coverage of Leadership and Management for Safety (L&MfS) aspects in PSRs needs to reflect their level of importance and draw upon the persistent worldwide lessons.

Aims of the L&MfS Review

1. The review should be relevant and challenging:

***Relevant***

* There should be a clear focus on nuclear safety.
* The PSR should show that L&MfS processes and practices are appropriate and proportionate to the specific hazards, risks, scale of operations and key safety claims made in the safety case.

***Challenging***

* The PSR should show evidence of an open-minded, critical, challenging review of L&MfS, not just a description of existing processes or assertions of effectiveness.
* The review should search for potential weaknesses and areas for improvement, rather than focus on arguments in support of the status quo.
* The claims made for L&MfS processes and practices should be evidence based, i.e. a review of effectiveness in practice and achievement of desired outcomes not just apparent suitability on paper.

Scope of the Review

1. The review should be sufficiently wide-ranging to encompass key facets of leadership and management for safety. The licensee can determine how the review is structured but the following documents could be used for guidance on the scope: Safety Assessment Principles (SAPs) on Leadership and Management for Safety (MS.1 to MS.4 in [3]); Function and Content of a Safety Management Prospectus [20]; and Application of the Management System for Facilities and Activities [21].
2. The SAPs L&MfS principles MS.1 to MS.4 cover leadership, capable organisation, decision making and learning. The principles provide a good basis for the ONR to examine the PSR regardless of how the licensee has structured the review or its management system.
3. Specific areas that the review should consider, following the aims set out above, include:

***Leadership***

* How effective is the organisation’s approach to the governance of nuclear safety (including the systems and processes for monitoring, directing and controlling activities from the licensee board and executive team downwards)?
* How well does the organisation understand and demonstrate the attributes of a positive safety culture (including reviews and improvement plans)?
* Are the leadership active and effective in promoting and implanting robust standards for nuclear safety and a positive safety culture?
* Is there open, honest and effective communication throughout the organisation and with contractors, particularly on nuclear safety matters?
* Is the management system ‘fit for purpose’ to meet nuclear safety requirements (including clarity of standards and expectations, appropriate and usable procedures, continual review and improvement)?

***Capable Organisation***

* Are the organisational design principles and the organisational structure appropriate to meet the nuclear safety needs of the business (particularly if the needs have changed)?
* Is the organisational baseline adequate, with effective processes for maintaining an organisation with suitable resources and competences to deliver nuclear safety (including vulnerability analysis, succession planning, recruitment etc.)?
* Are organisational changes managed well and is due consideration given to the cumulative impact of changes or anticipated changes (including restructuring, changes of parent company, major changes to the activities of the site, e.g. entering decommissioning, or ‘care and maintenance’)?
* Does the competence assurance system (including knowledge management or transfer processes) define and deliver nuclear safety requirements?
* Are the policy and practices for using contractors appropriate (including the ‘make/buy’ balance, management and oversight of contractors and sub-contractors, consideration of potential vulnerabilities and contingencies)?

***Decision making***

* How is it ensured that nuclear safety is given appropriate consideration in decision making within the business (including the use of good quality information, diverse views and questioning of assumptions, exploration of all relevant scenarios that may threaten nuclear safety and due consideration of options)?
* How well is the principle of conservative decision making applied, in the interests of nuclear safety, when faced with uncertainty or the unexpected?
* Is there a healthy ‘challenge culture’ and appropriate internal challenge for decisions of all types at all levels that may impact upon nuclear safety (including, but not limited to, a strong ‘internal regulator’ function)?
* Are the performance indicators/metrics, particularly those used at senior levels, sufficiently relevant to nuclear safety and are there any significant gaps in coverage; are the indicators used in combination with other, qualitative sources of information (e.g. audits/reviews, operating experience?)

***Learning organisation***

* Is there an open and fair reporting culture (do managers encourage this)?
* How well are opportunities for learning captured, collated, considered and acted upon (is learning being embedded)?
* Do event investigations/root cause analyses identify and address systemic issues (underlying leadership, organisational and cultural factors)?
* Does the organisation actively seek out and act upon external sources of learning (including non-nuclear sectors)?
* Is there an adequate range of self-evaluations and independent evaluations (including cross-cutting themes such as leadership and culture)?
* Is there an integrated approach to organisational learning (pulling together lessons from internal and external events, investigations, evaluations, organisational changes etc.)?

Annex 2: Expectations for a Decommissioning PSR

1. The PSR for a facility or site undergoing decommissioning needs to consider current nuclear safety and also that ageing and other effects will not render the plant unsafe before the next PSR. In addition, for so-called ‘essential facilities’ (i.e. those where there is no reasonably practicable alternative other than continued operation, e.g. certain radioactive waste facilities), the review should consider the period of potential continued operation before the facility could be replaced or closed (a period of fifty years is suggested).
2. The PSR should also look forward to final decommissioning and Post-operational Clear-out (POCO), checking that there are no foreseeable circumstances that are likely to be a threat to continued safe operation prior to this time. For decommissioning sites, this aspect of the PSR should be carried out with reference to the site’s Decommissioning Plan. If no such plan currently exists, the Licensee needs to provide one to support the PSR.
3. The scope of the PSR needs to reflect the type of operations being undertaken at the facility and it is unlikely that the scope used for PSRs when the facility was in normal operations will be appropriate. The scope of a decommissioning PSR should include the following components of the site’s safety case, so that the continuing validity of identified limits and conditions may be confirmed:

* All site operations and processes affecting nuclear safety (including the storing of wastes and contaminated land).
* The procedural documentation and other records kept to support these and other likely future operations and processes.
* Age-related degradation mechanisms and life-limiting features.
* The maintenance, inspection and testing regime.
* The updated radioactive inventory.
* The assessment of hazards and risks.
* Plans and drawings referred to in the safety case.
* The facility condition and configuration, and in particular whether this continues to reflect what is assumed in the safety case. Plant walk-downs may be helpful in reviewing these aspects.
* The condition of the site infrastructure (e.g. buildings) and whether this is suitable to support the safety case.
* Site services (and in particular Radiation Protection and Emergency Planning).
* The site’s management of safety arrangements and resources available for their implementation.
* Dependencies on other facilities and services provided externally.

1. For facilities or sites where decommissioning activities are programmed, a strategy for developing and managing the safety case as it evolves during the decommissioning process should be documented and submitted to the ONR prior to the start of work either as part of a Decommissioning Safety Case or as part of a PSR submission if a complete review is being carried out at that stage. The strategy should show how the safety case for the project will remain live and valid at all stages, and indicate how the progressive reduction of hazard will be achieved. Where activities may increase risks temporarily (for example to enable remedial work, facility installation or waste retrievals to be carried out) the submission should set out and justify the change in risk profile. Guidance on the management of radioactive materials and radioactive waste [22] should be noted.
2. For a decommissioning site the review should consider whether the date of the next PSR (normally at ten-yearly intervals) is appropriate, and in particular whether the next formal review should be brought forward in the light of any age-related topics and in particular because of ageing mechanisms or planned changes in future activities on the site.
3. Where facilities are either being defueled or placed into POCO in preparation for decommissioning, within the forthcoming PSR cycle, this will affect how the review is undertaken. ONR expectations are that in these circumstances a PSR will still be undertaken. However, the treatment of identified shortfalls should be undertaken in a proportionate manner which takes into account the following factors (this list is not exhaustive) when identifying to an ALARP solution:

* Whether the identified hazard will continue into the decommissioning phase of the facility (e.g. building structure shortfalls)
* Whether the safety systems will be required for decommissioning/defueling (e.g. ventilation, waste handling etc.)
* Transient hazards that may arise during decommissioning
* If the facility is being replaced, the timescales for the new facility to come on-line taking into account any un-certainties
* Whether the facility will be decommissioned in phases (e.g. some areas of the facility may remain operational whilst others are in POCO)
* The availability of other facilities for hazard removal e.g. stores etc.

1. TAG 051 [14] notes that the safety cases should be re-written prior to a facility entering decommissioning in order to ensure that the engineering proceeds in a manner that provides confidence that the safety requirements will be met. In addition TAG 026 [13] – Decommissioning notes that in determining the frequency of reviews, the licensee should consider aligning periodic reviews with any major changes in the facility or hazard(s) which may arise well before an otherwise planned periodic review. Thus, a PSR may be brought forward to align with the end of a facilities operating life. This will enable the PSR to align with the future operations being undertaken in the facility and ensure that the ALARP solutions are appropriate.
2. If a PSR is undertaken close to the end of its operating life e.g. within two years of shutdown, this may have an impact on the identified ALARP solutions for any identified shortfalls e.g. any solutions that will take a long time to implement may be discounted unless they will benefit the decommissioning operations, however short term solutions would still be expected to take their place or, if necessary, the cessation of operations brought forward. All of these factors, and others, must be considered when coming to an appropriate ALARP solution. TAG 005 Guidance on the Demonstration of ALARP [3] contains further details.

Annex 3: Expectations for the Coverage of Radiological Protection in PSR

**Purpose**

1. There are significant radiological protection challenges during the lifetime of a nuclear licensed site, and appropriate arrangements need to be in place to restrict exposures SFAIRP. Under current international guidance from the IAEA [12] radiological protection is regarded as an overarching safety factor, to be considered throughout the other fourteen safety factors it describes. However, GB licensees have generally provided specific radiological protection safety cases when a PSR assessment is undertaken. This annex provides a guide to ONR’s expectations of a PSR from a radiological protection perspective.

**Aims of ONR’s Radiological Protection Review**

**ONR’s aim is to ensure that:**

* The licensee has conducted an adequate review of the radiological protection aspects of their safety case. The claims and arguments identified in the PSR are supported by appropriate evidence supplied or readily available for ONR to sample.
* The licensee has identified any areas for improvement and provided an appropriate programme to address them.
* The licensee has provided a summary of worker dose as well as estimated doses to the public from direct radiation over the past 10 years as well as future projected doses for the next 10 years. In addition any information on any factors that might cause it to change in the next 10 years.
* The licensee has provided appropriate detail on the status of the plant and has identified the potential radiological protection challenges over the next 10 years.

**Scope of ONR’s Radiological Protection Review**

1. The licensee’s PSR should encompass key aspects of radiological protection. The licensee can determine how the review is structured but the following documents could be used for guidance on the scope:

* Safety Assessment Principles (SAP) on Radiological Protection (RP.1 to Rp.7) [4].
* NS-TAST-GD-004 – Fundamental Principles [23].
* NS-TAST-GD-038 – Radiological Protection [24].
* Ionising Radiations Regulations 2017 (IRR17) Approved Code of Practice and Guidance [25].

1. The SAPs addressing fundamental principles (FP.1 – FP.8), radiological protection (RP.1 - RP.7) and accident management (AM.1) are those most relevant to the assessment of the adequacy of the PSR from a radiological protection perspective. In addition, the adequacy of the PSR to secure compliance with the legal requirements of IRR17 should be examined.

**Areas for ONR Radiological Protection Review**

1. There are several areas that should be considered when undertaking a radiological protection PSR review. Below is a non-exhaustive list of areas the ONR radiological protection assessor may consider.

***Radiation Exposure***

* What analysis has the licensee provided regarding individual and collective occupational doses (i.e. workers, contractors) and public doses for the plant over the past 10 years?
* If there are anomalies identified in the licensee’s analysis of occupational and public doses, what explanation has been provided for the anomalies, and what action has the licensee undertaken to mitigate reoccurrence and ensure doses remain ALARP?
* What procedures are undertaken if a worker / contractor exceed the dose constraint / action level stipulated by the licensee for a planned operation at a plant? Has this occurred over the past 10 years, and what measures have been undertaken to mitigate reoccurrence?
* What engineered radiological protection controls (e.g. shielding) are in place to minimise dose to workers and members of the public? Are these still adequate for the current state of the plant?
* What measures has the licensee put in place to monitor dose trends and to maintain a continuous focus on ensuring that doses remain ALARP?
* What information has been provided regarding collective dose from higher dose activities (e.g. statutory outages, intrusive maintenance, decommissioning)? How has the licensee restricted exposure for these activities to ensure that doses are ALARP?
* If the plant is to undergo a change in operation (e.g. statutory outages, intrusive maintenance, decommissioning, entering care & maintenance (C&M)) over the next 10 years, what analysis has the licensee provided regarding dose predictions and to ensure that doses remain ALARP?

***Radiological & Contamination Events***

* What analysis has the licensee provided regarding radiological and personal or plant contamination events over the past 10 years?
* What learning has the licensee taken from such events and what measures have been put in place to prevent reoccurrence?
* If there have been any contamination / radiological events of greater significance or reoccurrence of similar types of event that have occurred on plant over the past 10 years, what specific actions were undertaken during the event and what controls were implemented to prevent a re-occurrence?
* Radiological Protection Management & Staff Resource
* What is the current radiological protection resource on the plant and how has the licensee demonstrated there is appropriate radiological protection resource at present?
* What are the likely radiological protection resource requirements for the next 10 years and what plans are in place to achieve this?
* How is knowledge management undertaken at the plant from a radiological protection perspective?

***Training***

* What are the current radiological protection training arrangements at the plant for workers, contractors and visitors?
* How do employees and contractors with radiological protection responsibilities demonstrate being SQEP for their roles?
* If the plant is currently changing or likely to change phase (e.g. from a decommissioning to C&M phase) will this affect training requirements for radiological protection on the plant? If so, what requirements for the modification of the RP training programme have been identified and how will they be implemented?

***Radiological Protection arrangements on plant***

* What information has been provided on the application of the hierarchy of control measures for restriction of exposure on the plant? Do examples provided align with current radiological protection guidance?
* How has the licensee demonstrated that designation of areas restricts exposure on plant?
* How is monitoring undertaken to restrict exposure on plant and control contamination at source?
* What are the current arrangements for the storage, control and accountancy of radioactive sources and radiation generators on plant?
* What arrangements in place for changeroom facilities on the plant? Are they in line with relevant good practice?
* What contingency arrangements are in place and are they appropriate for the plant?
* What benchmarking with other licensee’s or international organisations has been undertaken?
* What relevant good practice has been initiated?

***Work Documentation***

* To support the licensee’s PSR submissions, there should be a selection of radiological protection documentations to sample, which might include:
  + Radiological Protection Standards for the plant
  + Radiological Risk Assessments
  + Local Rules
  + Training Records
  + Surveys
  + Contingency Plans
  + Dose investigations
  + Company Standards
  + Source Store Accountancy

***Decommissioning*** *(for plants which are preparing for decommissioning in the next 10 years)*

* What are the main radiological challenges facing the plant over the next 10 years from a decommissioning perspective?
* Have environmental issues such as ageing or corrosion resulted in or likely to result in degradation of the building and structures? If so, how has the licensee demonstrated that radiological protection arrangements are adequate?
* What are the radiological arrangements in place for when the plant enters C&M phase if this is to occur within the next 10 years?

Table 1: WENRA Safety Reference Levels

| **SRL** | |
| --- | --- |
| **Reactor Harmonisation SRLs - Issue I** | |
| 2.3 | The Periodic Safety Review shall be used to confirm whether ageing and wear-out mechanisms have been correctly taken into account and to detect unexpected issues. |
| **Reactor Harmonisation SRLs - Issue P** | |
| 1 | Objective of the periodic safety review |
| 1.1 | The licensee shall have the prime responsibility for performing the Periodic Safety Review. |
| 1.2 | The review shall confirm the compliance of the plant with its  licensing basis and any deviations shall be resolved. |
| 1.3 | The review shall identify and evaluate the safety significance of  deviations from applicable current safety standards and internationally recognised good practices taking into account operating experience, relevant research findings, and the current state of technology. |
| 1.4 | All reasonably practicable improvement measures shall be implemented by the licensee as a result of the review, in a timely manner. |
| 1.5 | An overall assessment of the safety of the plant covering the period until the next PSR shall be provided, and adequate confidence in plant safety for continued operation demonstrated, based on the results of the review in each area. This assessment shall highlight any issues that might limit the future safe operation of the plant and explain how they will be managed. |
| 2 | Scope of the periodic safety review |
| 2.1 | The review shall be made periodically, at least every ten years. |
| 2.2 | The scope of the review shall be clearly defined and justified. The scope shall be as comprehensive as reasonably practical with regard to significant safety aspects of an operating plant and, as a minimum the following safety factors shall be covered by the review:  (a) Plant design;  (b) Actual condition of structures, systems and components (SSCs) important to safety;  (c) Equipment qualification;  (d) Ageing;  (e) Deterministic safety analysis;  (f) Probabilistic safety assessment;  (g) Hazard analysis;  (h) Safety performance;  (i) Use of experience from other plants and research findings;  (j) Organization, the management system and safety culture;  (k) Procedures;  (l) Human factors;  (m) Emergency planning;  (n) Radiological impact on the environment. |
| 3 | Methodology of the periodic safety review |
| 3.1 | The review shall use an up to date, systematic, and documented methodology, taking into account deterministic as well as probabilistic assessments. |
| 3.2 | Each area shall be reviewed and the findings compared to the licensing requirements as well as to current safety standards and practices. The safety significance of all findings shall be evaluated using an appropriate approach. A global assessment shall consider all findings (positive and negative) and their cumulative effect on safety, and shall identify what safety improvements are reasonably practicable. |
| **Waste and Spent Fuel Storage SRLs – March 2010** | |
| S-59 | The licensee shall carry out at regular intervals a review of the safety of the facility (PSR). The review shall be made periodically, at a frequency which shall be established by the national regulatory framework (e. g. every ten years). |
| S-60 | The scope and methodology of the PSR shall be clearly defined and justified. The PSR shall confirm the compliance with the licensing requirements. It shall also identify and evaluate the safety significance of differences from applicable current safety standards and good practices and take into account the cumulative effects of changes to procedures, modifications to the facility and the operating organization, technical developments, operational experience accumulated and ageing of SSCs. It shall include consideration of the acceptance criteria for waste and spent fuel packages and unpackaged spent fuel elements and any deviation from these criteria during storage. |
| S-61 | The results of the PSR shall be documented. All reasonably practicable improvement measures shall be subject to an action plan. |
| **Decommissioning SRLs** | |
| D71 | The licensee shall carry out at regular intervals a review of the safety of the facility (a periodic safety review). |
| D72 | The review shall confirm the compliance of the decommissioning activities and states with its licensing requirements and any deviations shall be resolved. It shall also identify and evaluate the safety significance of deviations from applicable current safety standards and best practices and take into account the cumulative effects of changes to procedures, modifications to the facility and the decommissioning  organisation, technical developments, decommissioning experience accumulated and ageing of SSCs. |
| D73 | All reasonably practicable improvement measures shall be taken by the licensee as a result of the review. |
| D74 | A periodic safety review shall be carried out at least every ten years. If the latest consolidated case has been produced in accordance with the general principles of periodic safety review, then the ten year period starts from the date of that case. |
| D75 | The scope and methodology of the review shall be clearly defined and justified. As a minimum the following areas shall be covered by the review:   * assessment of the monitoring and surveillance data, and of the operating experience to determine the actual condition of systems, structures and components * updated radioactive inventory * current safety analyses and their use * organisational arrangements * radiation protection arrangements * safety performance and the effectiveness of safety and quality management * staffing and qualification of staff * emergency preparedness * radiological impact on the public and on the environment * waste storage conditions * ageing of the safety significant structures, systems and components * advances in science and technology * changes in the environment of the facility, including external natural and man-made hazards * changes in regulations * feedback from past operations * feedback from similar facilities |

Table 2: Indicative Programme for a PSR

For a multi-plant site this programme should be followed for each PSR separately.

| **Point in time\*** | **Activities expected to be done by the relevant point in time** |
| --- | --- |
| **SD - 2 years** | * Licensee has completed the PSR plan and provides ONR with a timetable of activities. * ONR and licensee discuss scope of work and ONR’s expectations. |
| **SD - 1 years** | * Licensee has identified significant areas for improvement and/or analysis, and demonstrates that associated work has commenced. ONR advised of proposals. * ONR advises licensee of anticipated problems. |
| **SD** | * Licensee presents the PSR Submission, together with a progress report on improvements that are underway. |
| **SD + 9 months** | * ONR makes available to the licensee its findings on the PSR Submission. |
| **SD + 1 year** | * The 'Decision Date'. * The latest date by which the licensee should complete the improvements it has identified in the PSR (refer to paragraph 5.60). * ONR should confirm its decision in writing to the licensee regarding future activities on the facility encompassed by the PSR. * Licensee confirms the programme for addressing ONR findings. * ONR may issue a press release on a decision for continued operation. |
| **SD + 15 to 18 months** | * Where appropriate ONR may publish a report on the PSR assessment and findings, including the licensee's programme for further work. Where a public report is produced a press release should also be issued via the Press Office. |
| **SD + 3 years** | * Licensee confirms completion of all outstanding identified work, including ONR findings, except where agreed otherwise. * Where appropriate ONR may produce a close-out report and issue a press release. |

\* **SD** denotes PSR **S**ubmission **D**ate (a change from the previous use of ‘X’ dates).

**NOTE:** As stated, these are indicative timescales. If a licensee wants to adopt an alternative approach, this should be discussed with ONR in advance.

1. The Safety Directors’ Forum is a voluntary organisation with a vision to promote and maintain a safe, secure, sustainable UK Nuclear Industry. To help achieve this vision, it produces and issues guidance to the nuclear industry. https://www.nuclearinst.com/Safety-Directors-Forum [↑](#footnote-ref-1)